

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

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In re application of

Docket No: Q58580

II, NORITAKA, et al.

Appln. No.: 09/509,677

Group Art Unit: 1617

Confirmation No.: 3130

Examiner: S. HUI

Filed: March 30, 2000

For: ORAL ADMINISTRATION PREPARATION

RESPONSE TO ADVISORY ACTION

Commissioner for Patents  
Washington, D.C. 20231

Sir:

The Advisory Action mailed October 1, 2002, indicates that the Amendment filed September 12, 2002, was not entered because the amendments to the claims raise new issues that would require further consideration and/or search by the Examiner, e.g., the compounds recited in new claims 26-30.

In response Applicants submit a CPA herewith and request that the Amendment filed on September 12, 2002, be entered and considered on the merits and in view of the following additional comments.

In the Advisory Action, the Examiner states that the amendment to the specification replacing the term "corrective" with "flavoring agents" is considered as raising a new matter issue.

Applicants respectfully submit that one of ordinary skill in the art would recognize the compounds listed in the specification as flavoring agents, as indicated in the Amendment filed on

Response to Advisory Action  
U.S. Application No. 09/509,677

September 12, 2002. In support thereof, Applicants submit a copy of the relevant portion of Remington's Pharmaceutical Sciences, widely used by pharmacists and those of ordinary skill in the art of pharmaceutical sciences and making pharmaceutical formulations, which identifies flavoring agents and discusses flavoring methodologies. Thus, Applicants respectfully request reconsideration of the statement that the amendment to replace "corrective agents" with "flavoring agents" to correct a translation error is new matter in view of the fact that the disclosed agents are commonly known to those of ordinary skill in the art as flavoring agents and would immediately be recognized as such.

With respect to the rejection under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, that the specification does not contain sufficient guidance for one of ordinary skill in the art to select compounds useful in the practice of the present invention in light of the unpredictability of the pharmaceutical arts, Applicants respectfully submit that the specification clearly provides guidance sufficient for one of ordinary skill in the art to practice the claimed invention. Specifically, examples of compounds within the scope of the invention are provided and common structural characteristics between compounds useful in the practice of the claimed invention are described. Further, it is known in the art that there is a close relationship between chemical structure and taste as supported by Remingtons' Pharmaceutical Sciences submitted herewith. See, e.g., page 1291, 1<sup>st</sup> column, beginning at the section entitled "Correlation of Chemical Structure with Flavor and Odor" through col. 2, line 5. Thus, Applicants submit that one of ordinary skill in the art is sufficiently enabled by the present specification, and in view of the knowledge within the art, to practice the claimed invention.

Response to Advisory Action  
U.S. Application No. 09/509,677

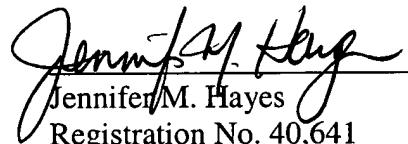
With respect to the rejection under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, that the terms “unpleasant taste” and “bitter taste” are relative terms, Applicants respectfully submit the fact that different panelist give different marks to the same formulation is not dispositive of indefiniteness as almost all test, scientific or objective, have some degree of variance, or margin of error, which is acceptable within the specific field. The proper inquiry is whether one of ordinary skill in the art would understand what is claimed in light of the specification. In view thereof, Applicants respectfully submit that the present specification provides a standard for measuring the degree of bitterness based upon the results of the sensory test provided and therefore, one of ordinary skill in the art would be sufficiently apprised as to the scope of the invention.

In regard to the prior art rejections, Applicants submit that the Examiner has not provided a reasonable technical basis for the assertion that the additional polymethacrylate polymer taught by Pearmain would not materially change the basic and novel characteristics of the claimed invention and therefore Applicants respectfully submit that the rejection is improper. With respect to Hoshino, it does not appear as if the Examiner even considered the arguments that Hoshino is not directed to the improvement of the unpleasant taste of drugs since the drug, sucralfate, has no taste. In support of the argument made in the Amendment filed on September 12, 2002, Applicants submit a sworn translation of the Japanese Pharmacopoeia in which it is indicated that sucralfate has no taste. Thus, Applicants submit that the Examiner has not made a *prima facie* showing of obviousness based upon the combination of Hoshino and Pearmain et al for the reasons set forth herein and the reasons already of record.

Response to Advisory Action  
U.S. Application No. 09/509,677

Applicants respectfully request reconsideration of the Amendment filed on September 12, 2002, the arguments made therein and the arguments made herein and withdrawal of the rejections.

Respectfully submitted,



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